

Attorney Docket No.: **KUZ-0021**  
Inventors: **Suzuki et al.**  
Serial No.: **10/517,468**  
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**REMARKS**

Claims 1-12 are pending in the instant application. Claims 1-12 have been rejected. Claims 6, 7 and 10 as well as the specification have been amended to correct an inadvertent translational error in referring to the measurement of bending stiffness assessed by the Cantilever method as taught at page 5 of the instant specification and to correct inadvertent typographical errors noted in the claims and specification upon review of the application during preparation of this response. No new matter has been added by these amendments and entry is respectfully requested. Reconsideration is respectfully requested in light of these amendments and the following remarks.

**I. Objection to Specification**

The abstract has been objected to because the term  $\mu\text{mRa}$  is undefined. Accordingly, in an earnest effort to advance the prosecution of this case, Applicants are providing herewith a replacement Abstract wherein the term is defined. Support for this amendment is provided in the specification at page 11, lines 2-4.

Further, the title has been objected to as not descriptive. Accordingly, Applicants have amended the title

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in accordance with teachings in the specification at page 1, lines 5-6 and page 6, lines 14-19 to be more descriptive.

No new matter is added by these amendments.

Withdrawal of these objections is respectfully requested.

## **II. Objection to Claims 6 and 7**

Claims 6 and 7 have been objected to because the word "styrene" is misspelled. Accordingly, in an earnest effort to advance the prosecution, Applicants have amended the claims and the specification to correct this inadvertent typographical error.

Withdrawal of this objection is therefore respectfully requested.

## **III. Rejection of Claim 10 under 35 U.S.C. 112, second paragraph**

Claim 10 has been rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, the Examiner suggests that recitation of "hard and flexible degree" is neither clear nor sufficiently descriptive as to define precisely the attribute of the substrate being measured.

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Accordingly, in an earnest effort to advance the prosecution of this case, Applicants have replaced the phrase "hard and flexible degree" in claim 10 and the instant specification with --bending stiffness--, the term used by those skilled in the art to definitively describe the characteristic measured by the Cantilever method taught at page 5, lines 16-17, of the instant specification. As discussed during the Telephone Interview on February 19, 2008, this patent application was originally filed in Japanese and use of the phrase "hard and flexible degree" instead of --bending stiffness-- in the specification is an inadvertent translational error. Evidence of "bending stiffness" being the term of art used to definitively describe the characteristic measured by the Cantilever method is provided herewith. Specifically, Applicants are providing herewith an English language translation of Japanese Industrial Standard JIS L-1085 (1992), a document summary of Active Standard: ASTM D5732-95(2001) Standard Test Method for Stiffness of Nonwoven Fabrics Using the Cantilever Test and an Abstract by Wyser et al. (<http://www3.interscience.wiley.com/cgi-bin/abstract/84502503/ABSTRACT?CRETRY=1&SRETRY=0>) entitled Predicting and determining the bending stiffness of thin films and laminates.

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Withdrawal of this rejection is therefore respectfully requested.

**IV. Obviousness-type Double Patenting Rejection of Claims 1, 6-9, 11 and 12 and Rejection of Claims 1-12 under 35 U.S.C. 103(a)**

Claims 1, 6-9, 11 and 12 have been rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 6-8 of Chono et al. (U.S. Patent 6,139,866) in view of claim 5 of Wick et al. (U.S. Patent 6,129,929).

Claims 1-12 have also been rejected under 35 U.S.C. 103(a) as being unpatentable over Chono et al. in view of Wick et al.

The Examiner suggests that Chono et al. and Wick et al. teach a transdermal patch formulation comprised of a polyester-based backing layer and an adhesive layer comprising a drug and that Wick et al. teaches use of various forms of silica (i.e. fumed, granulated sand), which are well known in the art as conveying surface roughness or abrasiveness, the inclusion of which increases friction between the backing and adhesive layers allowing for greater stability of the overall formulation. The Examiner refers specifically to col. 4, lines 7-9 of Wick et al.

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Applicants respectfully traverse this rejection.

As discussed during the Telephone Interview on February 19, 2008, the instant invention is a patch comprising a substrate made of a drug containing adhesive layer and a polyester-based film, wherein the polyester-based film has a surface in contact with the adhesive layer which has a roughness from 0.05 to 0.8  $\mu\text{mRa}$ . Use of the polyester-based film prevents drug from migrating from the adhesive layer into the polyester-based film backing layer, while the roughened surface of the polyester-based film layer improves anchoring of the adhesive layer to the polyester-based film.

As also discussed during the Telephone Interview, contrary to the Examiner's suggestion in the Office Action, Wick et al. does not teach or suggest use of silica to convey surface roughness to increase friction between the backing layer and adhesive layers. Instead, Wick et al. teach the use of various forms of silica in rheological agents (thickeners) for **additional** patch layers that supplement the backing layer. See teachings in Wick et al. at col. 3, lines 49-50 and col. 3 line 49 through col. 4, line 17. This references does not teach roughening the surface of the backing layer or adhesion of the drug-

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containing adhesive layer to a roughened surface of the backing layer.

Chono et al. also fails to provide any teaching or suggestion whatsoever with respect to surface roughening and/or a polyester-based film with a surface roughness on the side of the polyester-based film in contact with the adhesive layer of from 0.05 to 0.8  $\mu\text{mRa}$ , as claimed.

Accordingly, this combination of references fails to provide the requisite teaching or suggestion of all claim limitations to render the instant claimed invention obvious.

Further, as shown by data presented in the specification at pages 26-30, the instant claimed invention embodies a functional transdermal patch formulation that inhibits the migration of drugs to the backing layer while exhibiting improved anchoring properties between the polyester-based film and the adhesive layer due to use of a polyester-based film as a backing layer with a surface roughness (Ra) (the central line mean roughness defined by JIS B0601) from 0.05 to 0.8.

The cited combination of references, which provides no teaching regarding surface roughness of the backing layer in contact with the adhesive layer, thus also fails to provide any reasonable expectation of success with respect to the

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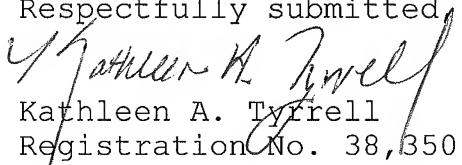
instant claimed invention with its improved anchoring properties.

Accordingly, the cited combination of references clearly fails to meet the basic tenets of obviousness as set forth in MPEP 2141 to render the instant claimed invention obvious under either obviousness-type double patenting or 35 U.S.C. 103.

Withdrawal of these rejections is therefore respectfully requested.

#### **V. Conclusion**

Applicants believe that the foregoing comprises a full and complete response to the Office Action of record. Accordingly, favorable reconsideration and subsequent allowance of the pending claims is earnestly solicited.

Respectfully submitted,  
  
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